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## **I. Basis for § 102(b) rejection**

The sale of a variety of geranium named Pensyb outside the United States only indicates that a geranium plant was in the possession of the public one year prior to the patent application filing date. To the extent that the sold variety was the same as the claimed variety, such a sale outside the United States is not a statutory bar under 35 U.S.C. § 102(b) which prohibits patenting of an invention which “was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country”.

Combining the sale of a claimed variety outside the United States with the scant disclosure in a Plant Breeders’ Rights (hereinafter, “PBR”) application or a published license agreement, constitutes improper use of prior art under 35 U.S.C. § 102(b) to build an “anticipation” rejection. It is well-settled that teachings of multiple references may not be combined to build an anticipation rejection. Studiengesellschaft Kohle, M.B.H. v. Dart Industries, Inc., 726 F.2d 724, 727, 220 USPQ 841, 842 (Fed. Cir. 1984).

The anticipation rejection in the present application has been characterized as based on the cited PBR applications or license agreement. The sale of a plant named Pensyb outside the United States is used to show that the claimed subject matter was in the public domain more than one year prior to the application filing date.

The rejection is flawed in its reliance on references which do not disclose every material element of the claim and its attempt to circumvent 35 U.S.C. § 102(b) to reject a claim on an invention that may have been sold outside the United States.

The Office Action of May 7, 2002 recognizes that a publication which is relied upon as prior art under 35 U.S.C. § 102(b) must be enabling. Moreover, it is admitted at pages 6-7 of the Office Action that the text of any of the cited publications “standing alone would not enable one skilled in the art to practice the claimed invention”. To account for the deficient teachings of the cited references, namely, their lack of an enabling disclosure, the

rejection is supplemented by possible prior public availability of the claimed plant. The Office Action asserts at page 6 that “when the claimed subject matter is disclosed identically by a reference, an additional reference may be relied on to show that the primary reference has an ‘enabled disclosure’”, citing In re Samour, 571 F.2d 559, 197 USPQ 1 (CCPA 1978) and In re Donohue, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985). Application of this asserted tenet of law to the present case is incorrect and not supported by case law.

The following comments set forth the proper standards for using multiple references in a § 102(b) rejection, namely, that an additional reference may be used to show that anticipatory prior art is in the public domain.

## **II. Use of multiple references to make a rejection under 35 U.S.C. § 102(b)**

It is well-established that a printed publication which discloses “every material element of the claimed subject matter” constitutes a bar under 35 U.S.C. § 102(b) if more than one year prior to an application’s filing date, it placed the claimed subject matter “in possession of the public”. In re Samour, 571 F.2d at 562, 197 USPQ at 3. See also, In re Donohue, 766 F.2d at 533, 226 USPQ at 621 (“It is well settled that prior art under 35 U.S.C. § 102(b) must sufficiently describe the claimed invention to have placed the public in possession of it”.)

There is some flexibility in the rule that only one reference may be used in an anticipation rejection. An additional reference may be used to prove that the primary reference discloses subject matter which is in the public’s possession. MPEP §2131.01. Pursuant to this exception, a secondary reference may be included in an anticipation rejection only when the primary reference in and of itself is an enabling disclosure. An additional reference may be used to show what the primary reference contains -- and not to supplement what the primary reference lacks. In both In re Samour and In re Donohue (each relating to patent applications on chemical inventions), an additional reference was relied upon to show

that the subject matter of a primary reference was available to the public. Neither case stands for the proposition that an additional reference may be used to supplement a non-enabling disclosure of a primary reference.

The claim at issue in In re Samour was directed to a specific chemical compound with the structure appearing in the claim. A first prior art reference disclosed the structural formula set forth in the claim, but the reference did not disclose a method for its preparation. Hence, the applicant argued that the first reference was non-enabling. In response, the Examiner cited an additional reference which disclosed a method for preparing similar types of compounds. On appeal from a final rejection, the Patent and Trademark Office Board of Appeals agreed that the additional reference provided a legally sufficient teaching of how to make the compound disclosed in the first reference. The court agreed that the mere recitation of the chemical formula of the claimed composition in a prior art reference would not have been sufficient to place the compound in the public's possession. Yet, the court was willing to consider relying on additional references:

solely as evidence that, more than one year prior to appellant's filing date, a method of preparing the claimed subject matter (DMMP) would have been known by, or would have been obvious to, one of ordinary skill in the art. Therefore, the key issue before us is whether the PTO, in making a rejection under 35 USC § 102(b) on a single prior art reference that discloses every material element of the claimed subject matter, can properly rely on additional references for such purpose.

Id. at 562, 197 USPQ at 4 (emphasis added).

The court maintained the rejection of the claim for the chemical compound based on the combined teachings of the printed publication disclosing the compound and a reference which disclosed a method for making similar compounds explaining that the additional reference cited in the § 102(b) rejection was "not relied on for a suggestion or incentive to combine teachings to meet the claimed limitations" (as in a rejection under 35

U.S.C. § 103), but, rather, to show that the claimed subject matter, **every material element of which is disclosed in the primary reference**, was in the possession of the public. Id. at 563, 197 USPQ at 4.

The Samour court did not import any disclosure from the secondary reference into the disclosure of the primary reference which taught every material element of the claimed compound. **Every material element of the claim was the structural formula of the claimed compound. The primary reference disclosed that same structural formula.** The secondary reference was only used to demonstrate that the claimed subject matter, **which was fully disclosed in a printed publication**, was available to the public.

A similar reasoning and result was found in In re Donohue where a claim also directed to a set of chemical compounds was rejected for anticipation by a primary reference that did not disclose methods of preparing the claimed compounds. Additional references relied upon by the United States Patent and Trademark Office taught how such compounds could be produced. The legal basis for upholding the rejection was outlined as follows:

It is well settled that prior art under 35 U.S.C. § 102(b) must sufficiently describe the claimed invention to have placed the public in possession of it. *In re Sasse*, 629 F.2d 675, 681, 207 USPQ 107, 111 (CCPA 1980); *In re Samour*, 571 F.2d at 562, 197 USPQ at 4; *see also Reading & Bates Construction Co. v. Baker Energy Resources Corp.*, 748 F.2d 64, 651-52, 223 USPQ 1168, 1173 (Fed. Cir. 1984). Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention. *See In re LeGrice*, 301 F.2d at 939, 133 USPQ at 373-74. Accordingly, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling. *In re Borst*, 345 F.2d 851, 855, 45 USPQ 554, 557 (CCPA 1965), *cert. denied*, 382 U.S. 973, 148 USPQ 771 (1966).

Id. at 533, 226 USPQ at 621 (footnote deleted).

The court specifically followed the rule of Samour to determine that the claimed subject matter was in the public's possession by looking to additional references.

The additional references utilized in this case (viz., Lincoln and Wagner) are not relief [sic] upon for suggestion or motivation to combine teachings to meet the claim limitations, as in rejections under 35 U.S.C. § 103. *In re Samour*, 571 F.2d at 563, 197 USPQ at 4-5. Such reliance would be pointless because Nomura [the primary reference] discloses every element claimed. The purpose of citing Lincoln and Wagner is, instead, to show that the claimed subject matter, as disclose [sic] in Nomura, was in the public's possession.

Id.

Both In re Samour and In re Donohue involved claims to a class of chemical compounds that was fully disclosed in a prior art reference. The secondary references in both cases were not employed to supplement any need for additional disclosure not present in the primary reference so that one skilled in the art could comprehend the scope of that referenced disclosure but only to show that the claimed chemical compounds were within the public domain. In other words, on their faces, the primary references were “enabling” because they taught every material element of the claimed subject matter. The only reliance on a secondary reference was to show that the claimed subject matter was in the public possession one year prior to the filing date of the patent applications for the chemical compounds.

This line of case law was recently followed in Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. et al., 246 F.3d 1368, 58 USPQ2d 1508 (Fed. Cir. 2001). Ben Venue and its codefendants alleged invalidity of a patent obtained by Bristol-Myers for a method of treating a cancer patient having steps of (i) premedicating the patient with a first drug and (ii) administering a second drug. The defendants argued that Bristol's claim was anticipated by a prior art reference which not only described treating patients with the second drug (i.e., the second step) but also suggested that “[f]urther studies are needed to see if *pretreatment regimens* [i.e., the first step], ... will permit the safe administration of this compound”. Id. at 1372, 58 USPQ2d at 1515-1516. At issue was whether the prior art reference which mentioned a pretreatment regimen was “enabling to one of skill in the art”

one year before the filing date of Bristol's patent application based on additional references and teachings to pretreat cancer patients. Following both Samour and Donohue, the court noted that enablement of an anticipatory reference may be demonstrated by another reference and restated the requirement of "a showing of each limitation of a claim in a single reference" for anticipation. Id. The court concluded that it was proper to look at other references to establish that the pretreatment regimen mentioned in the primary reference was in the public domain one year prior to Bristol's filing date. As was true for the claims at issue in Donohue and Samour, every material element of the claim in Bristol-Myers was present in the primary reference, namely, (i) premedicating a patient with a first drug and (ii) administering to the patient a second drug. The primary reference contained both of those limitations and additional references were only relied upon to show that premedicating a patient was within the public domain one year prior to the filing date of the patent application. No subject matter from the secondary reference was used to supplement the disclosure of the primary reference.

Hence, there are two requirements for using an additional reference to "enable" a primary reference in forming an anticipation rejection.

1. The primary reference must contain "every material element of the claimed invention"; and
2. The additional reference is relied upon only to demonstrate that the claimed subject matter was in the possession of the public one year prior to the filing date of the patent application.

### **III. Anticipation of plant subject matter by multiple references**

The cases of In re LeGrice, 301 F.2d 929, 133 USPQ 365 (CCPA 1962) and Ex parte Thomson, 24 USPQ2d 1618 (Bd. Pat. App. & Inter. 1992) are consistent with Samour, Donohue, and Bristol-Myers and do not support a proposition that a non-enabling publication about a plant may be made enabling by public use or sale of the plant itself.

**A. In re LeGrice**

At issue in LeGrice was whether a published catalog listing a variety of rose plants along with some botanical data and a color picture thereof barred patenting of that rose variety as a plant patent. It was established on the record that the color picture in the prior art catalog publication established identity at least in appearance between the rose plant illustrated in the catalog and the claimed variety.

**1. A plant cannot be produced from a disclosure thereof in a printed publication**

In determining whether the catalog was an “enabling” disclosure, i.e., sufficient to give the public possession of the rose plant, the court pointed out the following unique characteristics of plants as compared to manufactured articles. Plants protected by United States plant patents are asexually reproduced wherein the plant is propagated by divisions or cuttings to form clones, each of which is identical to its parent plant and to all other cuttings or clones taken from the parent plant. Id. at 937, 133 USPQ at 372. Even when the parentage of the claimed variety is set forth in a publication, no two seeds produced by cross-pollinating the parent plants can be expected to produce identical plants. Id. at 938, 133 USPQ at 373. The principles of heredity and plant genetics introduce innumerable possible combinations of genetic material which may result in equally innumerable distinct plants. Id.

The impossibility of producing a particular variety from a description thereof in a printed publication was a critical factor for the court in LeGrice. The court emphasized that the description of the invention in the printed publication must be an “enabling” description and that the proper test of an enabling description in a publication as a bar to a patent under § 102(b) is “whether one skilled in the art to which the invention pertains could take the description of the invention in the printed publication and combine it with his own



knowledge of the particular art and from this combination be put in possession of the invention on which a patent is sought”. Id. at 939, 133 USPQ at 374.

To put an inventor in possession of an invention based on a printed publication, the description therein must be:

So precise and particular that any person skilled in the art to which the invention belongs can construct and operate it without experiments and without further exercise of inventive skill.

Id. at 933, 133 USPQ at 369.

In 1962, the LeGrice court recognized that the knowledge of plant genetics made it impossible to reproduce a particular plant having specific botanical characteristics based solely on a description of the plant, even when the parent plants were known. Despite the many advances in biotechnology over nearly 40 years, that limitation on reproducing plants holds true.

Accompanying this response as Attachment A is a Declaration by Dr. Richard Craig, an expert in the field of horticulture. The details of Dr. Craig’s Declaration are not repeated herein, but should be appreciated for the explanation of the differences between asexually reproduced plants and sexually reproduced plants and the impossibility of generating a desired plant from a description thereof in a printed publication. As detailed in Dr. Craig’s Declaration, there is no possibility of recreating a particular variety via experimentation because of the endless possibilities when the genes of parent plants are combined to produce daughter plants.

Thus, when one makes a cross-fertilization of heterozygous parents, one cannot predict the specific combination of traits in the progeny. When a large number of genes have different allelic combinations in the parents, the possible genotypic combinations in the hybrid progeny approach infinity.

Craig Declaration at page 3.

Dr. Craig states that a description of a plant (such as the description in a PBR) cannot be used to recreate the plant.

Starting only from a photograph or a written description of a particular cultivar, a plant breeder cannot reproduce the cultivar. No person can independently create through fertilization and hybridization the exact genetic replica of another plant.

Craig Declaration at page 4.

Thus, it is still true today that a description of a particular variety cannot enable one skilled in the art to recreate that variety.

In the decision below LeGrice, the Board of Appeals had reasoned that since a description of a plant in a plant patent application is deemed sufficiently enabling to grant a patent, then a publication on a plant should be considered equally enabling to bar patenting. The LeGrice court pointed to two errors in that reasoning. First, § 162 specifically permits varying degrees of description in a plant patent while § 102(b) makes no such allowance regarding the sufficiency of the description in an anticipatory printed publication. Therefore, a plant patent application may be less specific than an anticipatory publication. Second, § 163 does not grant a right to exclude others from “making” a claimed plant but only to exclude others from asexually reproducing or selling the claimed plant. The statute reflects the reality that “there is no possibility of producing the plant *from a disclosure* as 35 U.S.C. § 112 contemplates” because one cannot make a plant, only asexually reproduce or sell it. Id. at 944, 133 USPQ at 378.

2. **The description of a plant and identification of a source to obtain the plant outside the United States is not prior art under 35 U.S.C. § 102(b) in a plant patent application.**

The LeGrice opinion does not directly address enablement of the printed publications on the claimed rose plant based on any other source, such as public availability of the plant.

However, implicit in LeGrice is that a publication describing a plant and a source to obtain that plant is not prior art to a plant patent application on that plant. The publications at issue in LeGrice included a national British publication on roses which disclosed the source of the rose plant at issue including the breeder's name and location and a catalog showing the rose plant. Although not specifically stated in LeGrice, the catalog indicated commercial availability of the rose plant. One skilled in the art, a plant breeder, could have determined the name and source of the rose plant and tracked down the rose plant. Despite availability of the rose plant (evidenced by the catalog), the court held the two publications to be incapable of placing the rose plant in the public domain. As should be true in this present application, the public use or sale of the rose plant outside the United States (such as via the catalog) were not of concern to the court in its analysis of statutory bars under 35 U.S.C. § 102(b).

The LeGrice opinion quotes from the appellant's brief therein stating at 935, 133 USPQ at 370-371 that "[p]rior public use and sale of a plant are avenues by which a plant enters the public domain." That quoted language omits a critical aspect of the prior use and sale statutory bar of 35 U.S.C. § 102(b), namely, that those prior activities must occur in the United States to constitute statutory bar.

LeGrice only holds that a printed publication cannot be considered to be an enabling disclosure of a claimed plant under Title 35 based on knowledge possessed by plant breeders. While the LeGrice court declined to characterize all plant publications as being irrelevant as printed publications under § 102(b) (allowing for developments in biotechnology), it noted that "the facts of each case [must] be carefully considered to determine whether the description of the printed publication in question *does in fact* place the invention in the possession of the public". Id. at 939, 133 USPQ at 374 (emphasis in original).

**3. The facts of LeGrice, non-enablement of a plant patent claim by a description of the plant, parallel the present case.**

In both LeGrice and here, the material elements of a plant patent claim are not set forth in the printed publication and there is no need to consult additional references, nor is it appropriate to do so.

A Plant Breeder's Rights publication or a published license agreement which refers only to a plant name or a species of a plant and a plant name cannot be considered to be so "precise and particular" that a skilled artisan could "construct and operate it without experiments and without further exercise of inventive skill." The ability to purchase a geranium named Pensyb one year prior to the application filing date is not equivalent to the ability to "construct and operate" a new geranium variety named 'Pensyb' based on one of the cited references. One skilled in the art may have learned of a geranium named 'Pensyb' – outside the United States. While public prior use and sale are avenues by which a plant enters the public domain, that prior use or sale must have occurred in the United States to rise to the level of a statutory bar. See 35 U.S.C. § 102(b).

A Plant Breeder's Rights publication could lead one skilled in the art to find a plant to purchase outside the United States which bears a name mentioned in the Plant Breeder's Rights application. That scenario is not one which renders the Plant Breeder's Rights publication enabling. It is simply a trail which leads to a sale of a plant outside the United States. There is no support in LeGrice or elsewhere for the proposition that sale of a named plant outside the United States automatically enables the publication of a Plant Breeder's Rights document or a published license agreement listing a plant with the same name.

**B. Ex parte Thomson**

Naturally, a different result was found in Ex parte Thomson when the claims in a **utility** application for a cotton cultivar were rejected over a prior art reference which **identically** disclosed the specification of the application for the cotton cultivar. The rejected claims were as follows:

1. A cotton cultivar having the designation Siokra (ATTC 40405).
2. Seeds of the cotton cultivar according to Claim 1.

Thomson, 24 USPQ2d 1618 (Bd. Pat. App. & Inter. 1992).

The Board of Patent Appeals and Interferences found that several prior art references disclosed the exact same cotton cultivar and seeds of that cultivar. Importantly, the Board found that “for enablement purposes, the descriptive words of the specification herein **do not differ substantially from** the disclosures of the cited publications”. Id. at 1621 (emphasis added). Moreover, the specification of the utility application was enabled by the availability of the claimed seeds deposited in the American Type Culture Collection (ATTC). The cited publications were also enabled by the public availability of the same cotton seeds. Id. As such, the public accessibility of the claimed seeds would have enabled the skilled artisan to make and use the claimed cotton cultivar and its seeds. Id. The Board upheld the rejection of the claims under 35 U.S.C. § 102(b) based on (1) prior art references that **identically** disclosed the claimed cultivar and (2) the opportunity for a skilled cotton grower to read the prior art references, purchase the commercially available seeds, and employ conventional techniques to obtain the claimed invention, namely, the plants and its seeds.

The Board distinguished LeGrice for three reasons.

First, actually following LeGrice, it recognized that each case is decided upon its own facts in determining whether the description in a printed publication is “adequate to put the public in possession of the invention and bar patenting of a plant” under § 102(b). Id. at 1620. The Board believed that sufficient advancements in plant eugenics warranted not following LeGrice’s rule on non-enablement of publications and expressed no doubt that the skilled artisan would be able to grow the claimed cultivar. As detailed in Dr. Craig’s Declaration, the Board was clearly mistaken. The “someday” of securing a plant invention by a description in a printed publication has not yet arrived. Regardless of the Board’s erroneous comments on genetic technology, **it remains axiomatic that each case must be decided on its own facts.** Id.

Second, the Board found it significant that for enablement purposes **the descriptive words of the specification did not differ substantially from the disclosures** of the cited publications. Id. In other words, all the material elements of the claim were disclosed in the primary reference. The specification was enabled by the deposit of the claimed seeds and the cited publications were also enabled by the deposit of the same seeds. The court noted that LeGrice did not consider the public availability of the rose plant at issue therein, and that the LeGrice holding was based on the specific printed publications. Public availability of the plant was one factor in the Thomson decision because the claim itself was enabled by public availability of the plant. However, a “significant” aspect of the 102(b) rejection was that the descriptive words of the prior art references did “not differ substantially” from the disclosures of the specification. Id.

Finally, the Board pointed out that whereas LeGrice was directed to patentability of plant patents, the patent at issue in Thomson was a utility patent which is afforded a broader scope of protection. Id. at note 1. Hence, the standard for anticipation by

a printed publication should be more broadly applied to the claims in a utility application than to a claim in a plant patent application. Id.

The Office Action in the present case incorrectly asserts that the same question was asked in Thomson and LeGrice of “what is required to enable” a printed publication describing a plant. The questions in those two cases must be different because Thomson involved a utility patent claim and LeGrice involved a plant patent claim -- and those are two different forms of statutory subject matter having different standards for enablement and infringement as discussed above.

It should be understood that the Thomson decision is consistent with Donohue and Samour in meeting the requirements for using additional references in a § 102(b) rejection.

First, every material element of the Thomson claim was set forth in the primary reference. (“We find it significant for enablement purposes the descriptive words of the specification do not differ substantially from the disclosure of the cited publications”). Thomson, 24 USPQ2d at 1621.

Second, the additional “reference” (the publicly available seeds) was cited solely to show that the plant described fully in the primary reference was in the public domain. As was true for Samour and Donohue, the Thomson rejection did not combine teachings of two references. The added reference only demonstrated that the plant material **fully** described in the primary reference was in the public domain.

**IV. Combining a PBR application or a published license agreement with public availability of a plant under 35 U.S.C. § 102(b) is improper in a plant patent application.**

Turning to the present application, the Office Action has also already acknowledged that none of the cited references standing alone would enable one skilled in the

art to practice the claimed invention. Unlike the situations in Samour, Donohue, and Thomson, every material element of the claimed subject matter does **not** exist in the various primary references.

**A. A PBR publication or a published license agreement does not disclose a plant having characteristics of the claimed variety or a plant identical to the claimed variety.**

To particularly point out how scant the information is in a PBR application, Attachment B contains the specification of the present application, rewritten to contain only the information which was present in the European Union PBR Application No. 98/0066, which presumably contains the most botanical data of all the primary references. The type of information which is included in a PBR application is quite unspecific and does not include the specific sizes, shapes, colors, and arrangement of various components of the plant. A comparison between the disclosure in EU 98/0066 and the present specification yields few similarities.

There is no indication of the origin of the plant described in EU 98/0066. Hence, the starting materials to produce the plant of EU 98/0066 is all dark purple-red geranium plants anywhere. Even if one were capable of somehow overcoming the current genetic technology barriers to reproduce a plant as described in EU 98/0066, there are numerous plants which could meet that description. The chance of actually creating the claimed variety having all the characteristics specified in the present application is essentially nil.

The claim in the present application is to “a new and distinct variety of geranium plant substantially as shown and described”. The claim refers not only to the photograph of the plant but also to the complete description of the plant set forth in 5 pages of the description. Each of those components of the description and of the photograph



constitute “the material elements of the claimed invention”. Those material elements of the claimed invention are not set forth in the primary references.

**B. The cited references do not inherently disclose the botanical characteristics of the claimed variety.**

As detailed above, there is very little in the cited primary references to indicate that the plant disclosed therein is definitely the claimed variety. Moreover, inherent characteristics of the claimed plant are not necessarily present in the plants of the cited references such that those references are anticipatory. This issue of inherent properties was addressed in Donahue, but the present case is distinguishable therefrom

The Donahue court disposed of an argument by the appellant therein that one of cited references (Nomura) failed to teach limitations in certain dependent claims to the compounds which specified solubility and melting point ranges stating that:

where...the dicarboxylic acid TMBP and dimethyl ester TMBP of Nomura are identical to the claimed invention, the properties of Nomura’s compounds are inherently the same as those of the claimed invention in the absence of proof to the contrary.

Id.

Certainly, a chemical compound such as the dicarboxylic acid TMBP or the dimethyl ester TMBP at issue in Donahue has a well defined chemical structure with directly corresponding physical properties including solubilities and melting point range. A claimed chemical compound by definition has certain immutable, inherent properties. A plant named ‘Pensyb’ does not. Every material element of a claimed chemical compound is found in its structural formula. A reference disclosing that structural formula discloses every material element of the claim.

An asexually reproduced plant is expected to have the same botanical characteristics as its parent plant. However, a mutation (spontaneous or otherwise) can cause an asexually reproduced plant to exhibit characteristics different from its parent plant. The

characteristics of the plant described in EU 98/0066 are not identical to the characteristics specified in the claimed plant. EU 98/0066 simply does not contain sufficient information to indicate what particular variety is described therein, despite having the name 'Pensyb'. As noted above, many geranium plants could fit the description in EU 98/0066. Hence, the present application is more than just a better description of a plant described in EU 98/0066-- it is **the** definitive description of the variety named 'Pensyb' claimed in the present application. Any attempt to cast the botanical characteristics of the present invention as inherent properties of a vaguely described plant named 'Pensyb' would be an improper interpretation of and reliance on Donohue relating to the inherent properties of chemical compounds.

A plant does not have a fixed, immutable formula as does a chemical compound. Notably, the LeGrice opinion does not contain reasoning that a plant disclosed in a publication has inherent characteristics identical to the same plant claimed in a plant patent application even though the record in LeGrice established identity between the claimed rose plant and the rose plant of the catalog. There was no consideration as to how the catalog plant could enable the plant described in the British journal based on inherent characteristics of the plant. Even though in Thomson the plant material of the publications was found to be identical to the claimed plant material, that finding was not based on any assumptions of inherent characteristics of the plant disclosed in the publications. There simply was no question that the specification and the publication did not differ substantially and that both referred to the **same** plant material for their respective enablements. Moreover, Thomson does not go so far as to stand for a position that **any** description of a plant is adequate prior art which may be enabled by prior availability of the plant. Thomson was determined on its own facts and its holding is limited thereto.

**V. Enablement of a PBR application or a license agreement as a prior art reference is inconsistent with current plant patent application examination practice**

The standards for compliance with 37 C.F.R. § 1.163 and 35 U.S.C. § 112, first paragraph in plant patent applications have become increasingly strict. Despite the variance in the degree of description in a plant permitted by 35 U.S.C. § 162, recent experience shows that many disclosures of plant patent applications are objected to and the claims therein are rejected under 35 U.S.C. § 112 first and second paragraphs which require as follows (emphasis added):

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to **enable** any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The November 2, 2001 Office Action in the present application included an objection to the disclosure under the first paragraph of § 112 and a rejection of the claim under the first and second paragraphs of § 112 for asserted lack of “a full, clear, and complete botanical description of the plant and the characteristics which define same per se and which distinguish the plant from related known cultivars and antecedents”.

Historically, the United States Patent and Trademark Office has not considered the information in a PBR publication (much less, a published license agreement) sufficient under §§ 112 and 162. More recently, even significantly more complete disclosures (such as the original specification filed herein) are not considered to be sufficiently complete (not enabling) under the statute.

To now assert that a PBR publication somehow is enabling prior art is inconsistent with the examination practice of requiring detailed botanical information in plant patent applications. The United States Patent and Trademark Office cannot have it both ways of asserting a PBR publication as enabling prior art (alone or in combination with sale or use outside the United States) **and** rejecting reasonably detailed plant patent applications for lack of enablement. Moreover, this new interpretation of PBR publications as being enabling prior art is contrary to decades of plant patent examination policy and practice.

Future plant patent applicants can comply with the stricter interpretation of § 162 when submitting their applications, but they should not be faced with a prior art rejection based on a non-enabling PBR application.

## **VI. The Realities of Plant Breeding**

Time delays in breeding new plant varieties exist whether the breeding occurs in the United States or elsewhere. In the case of plants bred outside the United States additional testing and trialing in the United States must take place to make sure the new plants are adaptable to the climatic conditions in this country. This often takes several years before the plants are deemed acceptable and actually enter the United States market. Only a few varieties trialed and tested in the United States actually enter the United States market and it is not economically feasible to file immediately on every variety to be tested. The new patent policy requires that such immediate filing takes place thereby placing the foreign plant patent breeder at a distinct disadvantage.

It is well recognized that plants bred outside the United States must be tested and trialed in the United States to make sure the new plants are adaptable to the climatic conditions in this country. This often takes several years before the plants are deemed acceptable and actually enter the United States market. These time delays in breeding new plant varieties exist whether the breeding occurs in the United States or elsewhere.

A plant bred in Germany can be introduced much more quickly in Germany because it was bred and grown there from the outset. Therefore, there is often a sale in Europe more than one year before the United States plant patent application is filed. A sale outside the United States does not trigger a statutory patent bar and does not diminish the need to afford protection to foreign plant breeders seeking to introduce their horticultural developments into the United States.

This concept has been understood since at least the time that the Townsend-Purnell Plant Patent Act became law in 1930. The Plant Patent Act of 1930 was enacted “to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry.” H.R. 1129, 71<sup>st</sup> Congress, 2d Session (1930).

Today the plant breeder has no adequate financial incentive to enter upon his work. A new variety once it has left the hands of the breeder may be reproduced in unlimited quantity by all. The originator’s only hope of financial reimbursement is through high prices for the comparatively few reproductions that he may dispose of during the first two or three years. After that time, depending on the speed with which the plant may be asexually reproduced, the breeder loses all control of his discovery. Under the bill the originator will have control of his discovery during a period of 17 years, the same term as under industrial patents. If the new variety is successful, the breeder or discoverer can expect an adequate financial reward.

Id.

Under the current examination practice, rejection of plant patent applications by foreign breeders who have not yet introduced their discoveries into the United States cuts off their opportunities of reaping adequate financial reward in the United States. Plant varieties which are not ready for introduction into the United States, but were sufficiently developed in Europe to be introduced there, are not given the benefit of the patent system as was intended by the Plant Patent Act of 1930. Without that benefit, foreign plant breeders “only hope of financial reimbursement is through high prices for the comparatively few reproductions that [they] may dispose of during the first two or three years” following

introduction of varieties into the United States. Id. The Plant Patent Act of 1930 was adopted so that “plant patents will mean better agricultural products that will give the public more actual value for its dollar”. Due to the current rejection policy and to the detriment of the public, advances in agriculture made outside the United States may not reach this country.

This policy by the United States Patent and Trademark Office represents a radical departure from any previous policy in the area of plant patent law. It has been estimated that, under such a radical policy, 70% of the extant plant patents issued to foreign applicants in the United States are invalid.

Relying on use and sales outside the United States to turn a non-enabling plant disclosure into an enabling one was never contemplated by drafters of the Plant Patent Act, is not recognized by statute, is contrary to Patent Office policy from at least as early as the LeGrice decision (1962) and makes absolutely no sense to anyone skilled in the art. This new radical policy needs to be promptly reversed so foreign plant breeders again have opportunities in this country to file United States plant patent applications.

## **VII. Conclusions**

Withdrawal of the rejection of claim 1 is respectfully requested for the reasons detailed above and summarized as follows:

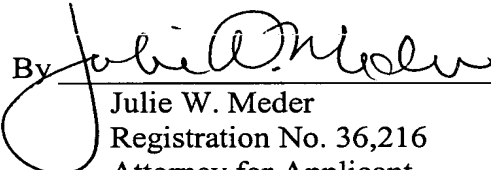
- A. The primary references do not disclose every material element of claim 1; they are not “enabling” references.
- B. The primary references cannot be read to describe a particular plant variety.
- C. The primary references’ scant disclosure (exemplified by EU 98/0066) may not be supplemented by an additional reference to supplement what the references fail to disclose; an additional reference can only be used to show that the plant disclosed in the references is in the public domain.

The current interpretation of statutory law by the United States Patent and Trademark Office is opposite to the longstanding relationship between Plant Breeder's Rights in foreign countries and United States plant patents and is counter to Federal Circuit case law dating back nearly 40 years.

Applicant respectfully requests that this new position by the Plant Patent Group be rescinded and that claim 1 be allowed.

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